K063577

## SECTION 2 – 510(k) SUMMARY

**Femoral Intrafix Screw and Sheath**

JAN 25 2007

| | |
|---|---|
| **Submitter's Name and Address:** | DePuy Mitek<br>a Johnson & Johnson company<br>325 Paramount Drive<br>Raynham, MA 02767 |
| **Contact Person** | Ruth C. Forstadt<br>Project Management Lead, Regulatory Affairs<br>DePuy Mitek<br>a Johnson & Johnson company<br>325 Paramount Drive<br>Raynham, MA 02767<br>Telephone: 508-977-3988<br>Facsimile: 508-828-3750<br>e-mail: rforstad@dpyus.jnj.com |
| **Name of Medical Device** | Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners<br><br>Common/Usual Name: Orthopedic Screw, Fixation Device<br><br>Proprietary Name: Femoral Intrafix Screw and Sheath |
| **Substantial Equivalence** | The Femoral Intrafix Screw and Sheath is substantially equivalent to:<br><br>Intrafix Screw and Sheath (K983560); the Milagro Interference Screw (K032717) and the Bio-Intrafix Screw and Sheath (K032167). |
| **Device Classification** | This device carries an FDA product code MBI and HWC, and is classified as Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners under 21 CFR 888.3040. |
| **Device Description** | The Femoral Intrafix Screw and Sheath are non-absorbable implants used to secure soft tissue grafts to the bone during cruciate ligament reconstruction. The two-part system consists of an expandable sheath that is inserted into the center of the tunnel. The sheath separates the graft strands and places them against the tunnel wall. The screw is inserted into the center of the expansion sheath. The screw expands the |

| | |
|---|---|
| | sheath and compresses the tissue against the bone. This device system consists of the following components:<br><br>Femoral Intrafix Screws and Sheaths in various sizes<br>*Various manual surgical instruments<br><br>* The various manual surgical instruments are Class I exempt (per 21 CFS 888.4540 "Orthopaedic Manual Surgical Instruments) stand-alone instruments used as an aide during the surgical application. |
| **Indications for Use** | Femoral Intrafix Screw and Sheath is indicated for fixation of soft tissue grafts during cruciate ligament reconstruction. |
| **Safety and Performance** | Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices.<br><br>Based on the indications for use, technological characteristics, and comparison to predicate devices, the Femoral Intrafix Screw and Sheath has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Mitek
A Johnson & Johnson company
% Ms. Ruth C. Forstadt
Project Management Lead,
Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

JAN 25 2007

Re: K063577
Trade/Device Name: Femoral Intrafix Screw and Sheath
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI and HWC
Dated: November 29, 2006
Received: November 30, 2006

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

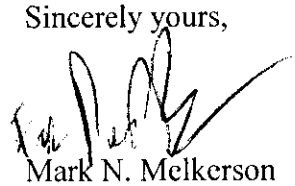
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): _____

**Device Names**: Femoral Intrafix Screw and Sheath

**The Femoral Intrafix Screw and Sheath** is indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of ___

**(Division Sign-Off)**

**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K062577

005_1